Remarks

Claims 1, 4, 5, 7-39 and 41-55 are pending in this application. Claims 4, 7, 21-22, 24, 26, and 54-55 are amended herein.

Claims 12-20, 27, 29-38, 40-47 are canceled herein, without prejudice to renewal. Applicants expressly reserve the right to prosecute this subject matter in a continuation or a divisional application.

Claims 4, 7, 22 and 54-55 are amended herein to correct matters of form. Support for the amendment of claims 21-22 and 24 can be found throughout the specification, such as on page 46, line 30 to page 49, line 9. Support for the amendment of claims 26 and 28 can be found throughout the specification, such as, but not limited to, page 51, line 23 to page 52, line 8; page 53, line 18 to page 59, line 15; and page 40, lines 7 to page 42 line 9.

Applicants believe no new matter is introduced by the foregoing amendments. These amendments are made solely to obtain a rapid allowance of the subject application.

Reconsideration of the pending claims is requested.

Allowable Subject Matter

Claims 1, 5, 7-11, 39 and 48 are allowed.

Claim 4 is objected to for a typographical error. Claim 4 is amended herein to recited "comprising the at least eight consecutive amino acids" as suggested in the Office action. This amendment renders the objection moot, and places claim 4 in condition for allowance.

Claims 54 and 55 are objected to for being in improper dependent form. Applicants respectfully disagree with this rejection.

Claim 54 is dependent on claim 1. Claim 1 is includes as subpart (2) an isolated polypeptide comprising the amino acid sequence set forth as SEQ ID NO: 1. Claim 54 is directed to an isolated polypeptide consisting of SEQ ID NO: 1. Thus, claim 1 and claim 54 differ in the transitional phrase.

MPEP § 211.03 describes transitional phrases, and confirms that the transitional phrase "comprises" means "includes." As set forth in MPEP § 2111.03:

> "The transitional phrases "comprising", "consisting essentially of" and "consisting of" define the scope of a claim with respect to what unrecited additional components or steps, if any, are excluded from the scope of the claim. The transitional term "comprising", which is synonymous with "including," "containing," or "characterized by," is inclusive or open-ended and does not exclude additional, unrecited elements or method steps.... The transitional phrase "consisting of" excludes any element, step, or ingredient not specified in the claim. *In re Gray*, 53 F.2d 520, 11 USPQ 255 (CCPA 1931); *Ex parte Davis*, 80 USPQ 448, 450 (Bd. App. 1948)"

Thus, the MPEP clearly acknowledges that a claim that includes the transitional phrase "comprising" is broader in scope from a claim that includes the transitional phrase "consisting of."

Claim 1 is directed to polypeptides that include the amino acid sequence set forth as SEQ ID NO: 1. A polypeptide that includes the amino acid sequence set forth as SEQ ID NO: 1 can have additional amino acids, but does not necessarily have additional amino acids. Thus claim 1 encompasses polypeptides that are limited to the amino acid sequence set forth as SEQ ID NO: 1. Claim 54 is directed to polypeptides limited to the amino acid sequence set forth as SEQ ID NO: 1. Thus, claim 54 is properly dependent on claim 1.

Solely to advance prosecution, claim 54 is amended herein to be in independent form rendering the objection moot. Applicants believe that claim 54 is now in condition for allowance. The Examiner is reminded that the addition of an independent claim cost the Applicants an additional $150. Thus, if after discussion with the Supervisory Examiner, it is determined that the claim 54 is properly dependent on claim 1, Applicants request that the Examiner call the undersigned so that the claim can be amended to be in dependent form, and request a credit of the excess claims fees.

Claim 55 is also objected to for being improperly dependent. Claim 55 can be amended to depend from claim 1. Claim 1 includes as sub-part (1) an isolated polypeptide comprising at least eight consecutive amino acids of amino acids 157-933 of SEQ ID NO: 1, wherein the isolated polypeptide is eight to ten amino acids in length and binds a Major Histocompatability Complex (MHC) molecule. Claim 55 is directed to an isolated polypeptide consisting of one of

SEQ ID NO: 3-10. Each of SEQ ID NOs: 3-10 includes at least eight consecutive amino acids of amino acids 157-933 of SEQ ID NO: 1, is eight to ten amino acids in length, and binds a Major Histocompatability Complex (MHC) molecule. SEQ ID NO: 3-10 are just individual embodiments of the genus of polypeptides claimed in claim 1. Claim 1 and claim 54 differ in the transitional phrase. As discussed above, MPEP § 211.03 describes transitional phrases, and confirms that the transitional phrase "comprises" means "includes." Thus, claim 1 is directed to polypeptides that include includes at least eight consecutive amino acids of amino acids 157-933 of SEQ ID NO: 1, is eight to ten amino acids in length, and binds a Major Histocompatability Complex (MHC) molecule, and encompasses polypeptides limited to the amino acid sequence set forth as one of SEQ ID NOs: 3-10. Thus, claim 55 is properly dependent on claim 1.

Solely to advance prosecution, claim 55 is amended herein to be in independent form, rendering the objection moot. Applicants believe that claim 55 is now in condition for allowance. The Examiner is reminded that the addition of an independent claim costs the Applicants an additional $150. Thus, if after discussion with the Supervisory Examiner, it is determined that claim 55 is properly dependent on claim 1, Applicants request that the Examiner call the undersigned so that the claim can be amended to be in dependent form, and request a credit of the excess claim fees.

Thus, Applicants believe that claims 4, 54 and 55 are also in condition for allowance, which action is requested.

Objection to Claim 47 and Claim 4

Claim 47 is objected to as being a substantial duplicate of claim 4. Applicants respectfully disagree. However, claim 47 is canceled herein rendering this objection moot.

Rejections Under 35 U.S.C. § 112, First Paragraph

Claim 24 and 25 are rejected under 35 U.S.C. 112, first paragraph, as allegedly not being enabled by the specification. Applicants respectfully disagree with this rejection.

The Office action states that the claimed methods are enabled for the detection of prostate tissue in a subject by detecting the polynucleotide of claim 7 in a sample from the subject, wherein detection of the polynucleotide indicates the presence of prostate tissue. However, the

Office action alleges that the claims are not enabled because SEQ ID NO: 2 is not differentially expressed between normal prostate and prostate cancer.

The Office action acknowledges on page 5, that the Applicants have fully enabled the detection of SV-NGEP in both prostate cancer and normal prostate. The Office action acknowledges that evidence has been reviewed documenting that SV-NGEP is expressed only in normal prostate and prostate cancer cells (Bera et al., 2004; Das et al., 2007). Claim 24 as previously pending was directed to the detection of either "prostate cancer or prostate tissue." Claim 24 did not include the limitation that the prostate cancer was differentiated from prostate tissue. Using the method of claim 24, a practitioner would identify a sample as including either "prostate cancer or prostate tissue." Thus, claim 24 as previously pending was fully enabled by the specification.

Solely to advance prosecution, claim 24 is amended to recite the detection of prostate *cells*, thereby rendering the rejection moot. Claim 25 depends from claim 24, and thus the rejection is also moot as applied to claim 25. In the unlikely event that this rejection is maintained, the Applicants request a telephone interview with the Examiner and her supervisor.

Claims 26-30 are rejected under 35 U.S.C. 112, first paragraph, as allegedly not being sufficiently described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected to make and/or use the invention. Claims 29-30 are canceled herein, rendering the rejection moot as applied to these claims. Applicants respectfully disagree with this rejection as applied to the claims 26-28 as amended.

Claim 26 is directed to methods for producing an immune response to the polypeptide of claim 1, by administering a therapeutically effective amount of the polypeptide of claim 1. Thus, this claim encompasses methods for the production of antibodies. These methods are described thoughout the specification, for example at page 31, line 26 to page 37, line 28; page 51, line 23 to page 52, line 8; and page 53, line 18 to page 59, line 15. The specification further discloses that these methods have been reduced to practice.

The presently claimed methods are fully enabled by the specification, as discussed in the following Wands analysis. For the Examiner's convenience, the Applicants have used the order of elements found in the Office action on pages 4-5:

(1) *The quantity of experimentation necessary:* Polypeptides comprising SEQ ID NO: 1 are fully described in the specification. The administration of polypeptides to animals, such as for the production of polyclonal and monoclonal antibodies is routine. A working example, describing the production of antibodies, is provided in the Examples section (see page 51, line 23 to page 52, line 8). Thus, very limited experimentation is required to administer a polypeptide and produce an immune response.

(2) *The amount of direction and guidance presented:* A substantial amount of direction and guidance is presented for administering polypeptides to a mammal to produce an immune response. The polypeptides are disclosed, for example, at page 21, line 21 to page 26, line 32. Methods for administering the claimed polypeptides to produce antibodies are disclosed at page 31, line 26 to page 37, line 28. Working examples of the administration of the claimed polypeptides to produce a B cell (and a T cell) response are disclosed at page 51, line 23 to page 52, line 8 and at page 53, line 18 to page 59, line 15; and page 40, lines 7 to page 42 line 9.

(3) *The presence of working examples*: The production of an immune response to the claimed polypeptides in both rabbits and mice is described at page 51, line 23 to page 52, line 8. Thus, the claimed methods have been fully reduced to practice.

(4) *The nature of the invention:* The claimed methods are directed to the administration of polypeptides in order to produce an immune response, such as for the production of antibodies.

(5) *The state of the prior art:* The administration of polypeptides to produce an immune response, such as to produce antibodies and T cells, is well known in the art. Indeed, citations to textbooks and standard protocols for the production of an immune response, such as, but not limited to the production of antibodies are provided in the specification, see, for example, page 32, lines 17-25; page 33, lines 1-4, 22 and 32-33; page 34, lines 1-10; page 35, lines 13-15 and 29-31; and page 55, line 28 to page 56, line 7. Thus, protocols for the production of a T and a B cell immune response are readily available to one of skill in the art.

(6) *The relative level of those of skill in the art:* The relative skill level of a molecular biologist or immunologist is high.

(7) *The predictability of the art:* The production of an immune response using established protocols is routine, as described above (see point 5). Working examples of the production of antibodies are provided in the specification.

(8) *The breadth of the claims:* The claims are limited to producing an immune response to a polypeptide specified in claim 1 (i.e., comprising either full length SEQ ID NO: 1 or 8-10 amino acid fragments of SEQ ID NO: 1 that bind MHC).

The Applicants submit that claim 26 as amended, and claims 27-28, which depend from claim 26, are fully supported by the specification. Reconsideration and withdrawal of the rejection are respectfully requested.

Request for Rejoinder

Claims 21-23 are amended herein to be directed to methods for detecting prostate cells in a sample from a subject; claims 21-23 depend from claim 1, or a dependent claim thereof.

The Office action dated July 28, 2008 asserted a restriction requirement between product and process claims. This Office action confirmed that if product claims were elected, withdrawn process claims that depend from or otherwise include all of the limitations of the allowed product claim would be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all o f the limitations of the patentable product should be rejoined and the process claims should be fully examined. Thus, examination of claims 21-23 is respectfully requested.

The Office action dated October 16, 2008 confirms that methods for detecting prostate tissue from a subject are enabled by the specification (see page 4 of the Office action).

Allowance of claims 21-23 is respectfully requested.

Conclusion and Interview Request

Applicants believe that the present claims are in condition for allowance, which action is requested. *If any issues remain prior to allowance, the Examiner is formally requested to contact the undersigned prior to issuance of the next Office action, in order to arrange a telephonic interview.* The Applicants have identified a number of specific points above that can be discussed with the Examiner and her supervisor. It is believed that a brief discussion of the merits of the present application may expedite prosecution. If any rejections are maintained, or any new rejection is assert, the Examiner is requested to contact the undersigned to set up a date and time for a telephonic interview. This request is being submitted under MPEP §713.01, which indicates that an interview may be arranged in advance by a written request.

Respectfully submitted,

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